IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of

Applicant	:	Petrus Besselink
Serial No.	:	10/528,044
Filed	:	March 16, 2005
Title	:	VASCULAR FILTER WITH IMPROVED STRENGTH AND FLEXIBILITY
Docket No.	:	BES 0009 PA
Examiner	:	Elizabeth Houston
Art Unit	:	3731
Conf. No.	:	2774

EFS Web Electronic Submission
July 27, 2010

Commissioner for Patents
P.O. Box 1450
Mail Stop Appeal Brief - Patents
Alexandria, Virginia 22313-1450

Sir:

APPEAL BRIEF

This is an appeal from the final rejection mailed March 24, 2010. A Notice of Appeal was timely filed on May 27, 2010. Our credit card payment in the amount of $270.00 (small entity) accompanies this Brief, per 37 CFR §41.20(b)(2).

Real Party In Interest

The real party in interest is the Assignee Memory Metal Holland BV, a corporation of The Netherlands, by assignment from the named inventor, which assignment has been recorded at the United States Patent & Trademark Office on August 17, 2005 at Reel 016411, Frame 0843.

Related Appeals and Interferences

None.

Status of Claims

Claims 1 through 6, 8 through 10, 13, 15 through 21, 41, 42, 48, 51, 52 and 55 though 59 stand rejected in the present application and are the subject of the present appeal.

Status of Amendments

All previous amendments have been entered. The Appellant has not filed any response or amendment subsequent to the March 24, 2010 final rejection.

Summary of the Claimed Subject Matter

Claims 1, 48 and 55 are the independent claims, all of which recite a medical device that can be inserted into a body lumen (such as arteries or veins). The device includes a membrane with reinforcement fibers coupled thereto such that a composite structure is formed. An expandable frame is attached to the composite structure to hold the membrane in a desired shape A concise explanation of the subject matter defined in the independent claims is set forth for each *in seriatim*.

Independent Claim 1

In independent claim 1, the medical device includes an expandable frame **450** attached to a composite structure made from a membrane **410** and reinforcement fibers **420**. The composite structure is mounted to the frame **450** at hinge sites **459**. These features are best shown at FIGS. 29 through 31 and described at page 31, line 25 through 28 of the original PCT specification. In addition, FIGS. 5 and 6, in conjunction with page 6, lines 3 through 4, explains that the composite nature of the membrane is of thin, flexible construction. Furthermore, page 7, line 11 states that thin filaments are embedded in the filter membrane to produce a composite structure with extreme flexibility and elasticity.

Independent Claim 48

Independent claim 48 recites that the medical device includes an expandable frame **450** attached to a composite structure made from a membrane **410** and reinforcement fibers **420** in the manner discussed above in conjunction with independent claim 1. In addition, the device includes an elongated member in the form of a guide wire **460** (as shown in FIG. 31) that is attached to the frame or composite structure to move the device through a vein, artery or related body lumen. In addition to the passages and drawings discussed above in conjunction with independent claim 1, the features of independent claim 48 that are particular to the elongate member are discussed at page 33, lines 6 through 30.

Independent Claim 55

Independent claim 55 recites a medical device that includes a composite structure made up of a membrane **410** coupled to fibers **420**, a frame **450** attached to the composite structure, and fibers **420** coupled to the frame. A guide wire **460** is coupled to the frame and composite structure through the fibers such that the composite structure and frame can be moved. The construction of the fibers to both the membrane and the frame enhances the devices structural integrity and operability. The nature of the device's construction is shown in FIGS. 30 and 31, and is described at page 29, line 27 through page 31, line 4, as well as at page 33, lines 6 through 8.

Grounds of Rejection to be Reviewed on Appeal

Claims 1-5, 8, 9, 13, 15, 18 through 21, 41, 42, 48, 51, 52 and 55 through 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,371,971 to Tsugita et al. (hereinafter Tsugita) in view of US Patent 5,836,962 to Gianotti (hereinafter Gianotti).

Claims 6, 10, 16 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita in view of Gianotti as applied to claims above, and further in view of US Patent 5,814,064 to Daniel et al. (hereinafter Daniel).

Arguments

I. The rejection of claims 1-5, 8, 9, 13, 15, 18 through 21, 41, 42, 48, 51, 52 and 55 through 59 under 35 U.S.C. 103(a) over Tsugita in view of Gianotti is improper, as nothing in their combination teaches or suggests the claimed medical device with a fiber-reinforced membrane for use in a body lumen as the Examiner suggests.

Each of the independent claims 1, 48 and 55 recite, among other things, that a frame is attached to a composite structure made up of reinforcing fibers and a membrane. The emphasis on the fiber reinforcement of the membrane is an important feature of the invention, as numerous places in the original specification discuss the improved structural integrity and operability of the device when such reinforcement is present. A particular example of this is noted at page 34, lines 27 through 30 of the original specification, where an expandable frame such that the composite structure relies upon the frame (when expanded) to hold the membrane in a desired shape so that the membrane is protected against incidental overload, tear propagation or related problems inherent in non-reinforced membranes. Likewise, page 7, lines 11 through 15 of the original specification recite that the resulting composite membrane has great flexibility, high strength and prevention of crack propagation to help to give the membrane a desired shape after deployment.

The Examiner recognizes in numbered paragraph 4 of the March 24, 2010 Office Action that Tsugita fails to include fiber reinforcement coupled to a membrane to form a composite structure, and then attempts to rectify this shortcoming by equating the braided fiber configuration of Gianotti to that of Tsugita. The Examiner correctly states in paragraph 11 of the March 24, 2010 Office Action that "the claims require a membrane and reinforcement fibers coupled to the membrane to form a composite structure", and then appears to use the fact that the structural shell **5** (shown, for example, in FIGS. 4 and 5 of Gianotti) is the equivalent of the claimed membrane, going so far as to state (again, at paragraph 11) that "[t]his is exactly what is taught by Gianotti. . . ." Upon closer inspection, the device of Gianotti provides no such structure, and as such does not remedy Tsugita's

shortcomings.

Specifically, Gianotti's so-called composite is a series of reinforcement fibers **4** embedded in both an elongate support **3** and an elongate shell **5**. There is nothing in the elongate composite construction of Gianotti that even remotely suggests a fiber-reinforced membrane as properly understood by recourse to the original specification. More particularly, the clear language of page 27, line 22 through page 28, line 13 of the original specification indicates as follows:

> In the present context, a "composite" structure is distinguished from other reinforced devices where discrete structural members are connected to or supportive of relative non-structural members without substantial integration of the two. By contrast, a composite structure includes at least a relatively non-loadbearing matrix member that surrounds (or embeds) a loadbearing reinforcement member such that the two are integrally formed to define a unitary member. With this understanding, a substantially monolithic membrane (made form, for example, a polymeric or related plastics material) merely attached to an underlying or overlying structural cage or basket (made from, for example, a metal or plastic material) is more akin to a "body-on-frame" structure rather than a "composite" structure. In the present invention, the first (matrix) material makes up the highly flexible filter membrane, where a pattern of holes in the membrane allows the flow of blood particles below a well defined size. The second (reinforcement) material is one or more fibers that possess high axial strength, but are thin enough to be flexible upon bending. The reinforcement is integrated with the membrane to create a composite structure with very flexible membrane areas where the blood is filtered, and extremely strong reinforcement fibers that take up excessive forces. The strength of the fibers prevents the membrane from tearing even in response to pulling or related moving forces, while their flexibility allows hinging at the points of attachment to the proximal frame and/or to an elongated member used for transporting the membrane to or from the location within the patient's body where the membrane is needed. The elongated member can be one of numerous conventional devices, including (but not limited to) a guide wire, a hollow tube, a tool for holding the aforementioned proximal frame, or a balloonable stent.

This notion of a thin, flexible, relatively non-loadbearing sheet-like membrane being coupled to a reinforcing fiber to produce an intraluminal medical device is further discussed in numerous

locations within the original specification, including page 31, line 1 that indicates that the membrane is thin, as well as at page 33, line 8 that notes that the membrane is only 5 microns in thickness. Such a construction is consistent with well-accepted definitions of a membrane. For example, according to *Webster's Ninth New Collegiate Dictionary* (1988 ed.), a membrane is "a thin soft pliable sheet or layer". Furthermore, the combined authority of MPEP 2106, which states that "[i]f an applicant does not define a term in the specification, that term will be given its "common meaning", along with case law holding that all words in a claim must be considered in judging the patentability of that claim against the prior art (see, for example, *In re Miller,* 169 USPQ 597, 600 ((CCPA 1971) and *In re Wilson,* 165 USPQ 494, 496 (CCPA 1970)) makes it clear that the Applicant clearly intended the composite structure recited in the independent claims to possess a relatively thin membrane coupled to reinforcement fibers rather than any combination of the purely fibrous mesh of Tsugita or the concentric reinforced fiber construction of Gianotti. To subscribe to the Examiner's interpretation of what it means to recite such a membrane would destroy the plain meaning of that claim requirement, and would therefore impermissible, as the standard for claim limitation construction under MPEP 2111 is not an unmoored "broadest reasonable interpretation" but a broadest reasonable interpretation that is consistent with the specification. Accordingly, the Examiner's assessment of the applicability of Gianotti to the proper understanding of the claimed membrane stands athwart well-established precedent.

Accordingly, the present rejection does not satisfy the requirements of a *prima facie* case of obviousness, as MPEP 2143.03 states that one of the requirements is that all of the claim limitations must be taught or suggested. Because there is no evidence that the combination of the Tsugita and Gianotti teaches or suggests the properly-construed composite feature with a fiber-reinforced membrane, the Examiner's continued reliance upon the proposed combination is violative of well-accepted patent practice, and must therefore be reversed.

II. The rejection of claims 6, 10, 16 and 17 under 35 U.S.C. 103(a) over Tsugita in view of Gianotti and further in view of Daniel is improper, as the latter patent does nothing to remedy the deficiencies in the former patents related to the fiber-reinforced composite structure.

Claims 6, 10, 16 and 17 depend from independent claim 1. For reasons discussed in Section I above, the Examiner's proposed combination of Tsugita and Gianotti fails to teach or suggest a composite structure made of a fiber-reinforced membrane as part of a medical device. Daniel also fails to contemplate a fiber-reinforced composite structure as understood by the passage reproduced above from the original specification, and as such is not helpful to the Examiner's position. Because the requirement under MPEP 2143.03 that all of the claim limitations must be taught or suggested is not met by the combination of Tsugita and Gianotti, and there is nothing in Daniel that corrects this deficiency, then at least this component of the tripartite test for obviousness has not been met, and as a logical concomitant, a *prima facie* case for obviousness for these dependent claims can no longer be justified.

Conclusion

For all of the above reasons, the Applicant submits that the Examiner's rejection of all of the claims is improper, and should be **REVERSED**.

Respectfully submitted,

DINSMORE & SHOHL LLP

By /John D. Reed/
John D. Reed
Registration No. 46,506

Fifth Third Center
One South Main Street
Suite 1300
Dayton, Ohio 45402-2023
Telephone: (937) 449-6453
Facsimile: (937) 449-6405
Email: john.reed@dinslaw.com

Claims Appendix

1. (Previously Presented) A medical device configured to be disposed within a body lumen, said device comprising:

a membrane;

reinforcement fibers coupled to said membrane to form a composite structure therefrom; and

an expandable frame attached to said composite structure to hold said membrane in a desired shape.

2. (Previously Presented) The device of claim 1, wherein said frame comprises a proximal end and a distal end and is made from a metallic material.

3. (Original) The device of claim 2, further comprising an elongated member configured to transport said device to an appropriate location in said body lumen.

4. (Original) The device of claim 3, wherein said elongated member comprises a guide wire attached to at least one of said frame or said composite structure.

5. (Previously Presented) The device of claim 4, wherein said proximal end of said frame is remote from said membrane.

6. (Original) The device of claim 5, further comprising pulling fibers connecting said proximal end of said frame to said guide wire to enable said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body lumen.

7. (Withdrawn) The device of claim 4, wherein said distal end of said frame is adjacent said membrane unit, and wherein said reinforcement fibers are connected between said distal end of said frame and said guide wire for enabling said device to be extracted from a delivery sheath by pushing

on said guide wire to impose a pulling force on said composite structure in order to introduce said device into said body lumen.

8. (Original) The device of claim 4, further comprising a plurality of slide rings, each of said slide rings connected to opposing ends of said device such that said slide rings are responsive to displacement forces imparted thereto by said guide wire.

9. (Original) The device of claim 8, wherein said reinforcement fibers are directly attached to one of said slide rings and said distal end of said frame.

10. (Original) The device of claim 9, further comprising pulling fibers connecting said proximal end of said frame to said guide wire for enabling said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body lumen.

11. (Withdrawn) The device of claim 9, wherein said proximal section of said frame is tapered to facilitate retraction of said frame into a sheath.

12. (Withdrawn) The device of claim 4, further comprising a pressure sensing tip coupled to said guide wire.

13. (Original) The device of claim 4, wherein said frame is configured to allow said guide wire to move freely in axial, radial, tangential and rotational directions within said frame when said frame is in an expanded state without influencing the position and shape of said device.

14. (Withdrawn) The device of claim 1, wherein said device is configured as one filter of a double filter system.

15. (Original) The device of claim 4, wherein said frame has elongated struts that define

attachment points at said proximal end to facilitate connection of said frame to said guide wire.

16. (Original) The device of claim 15, further comprising pulling fibers connected to said attachment points by means of attachment holes disposed therein.

17. (Original) The device of claim 15, further comprising pulling fibers connected to said attachment points by gluing or welding.

18. (Original) The device of claim 4, further comprising a hollow tube advanceable into a region at least partially enclosed by said composite structure when said composite structure is in an open state.

19. (Original) The device of claim 18, wherein said guide wire is configured to fit within said hollow tube.

20. (Original) The device of claim 18, wherein said tube is configured to perform at least one of a suction, flushing, inspection, measuring, clot-breaking, and retrieval device introduction functions while said tube is advanced into said at least partially enclosed region.

21. (Original) The device of claim 20, wherein said hollow tube is dimensioned to serve as a removal sheath for said device.

22. (Withdrawn) The device of claim 3, wherein said elongated member is configured to be detached from said frame.

23. (Withdrawn) The device of claim 22, further comprising:

a slide ring coupled to said device; and

a hollow tube disposed within said slide ring, wherein said hollow tube comprises a

longitudinally split distal end movably responsive to said elongated member such that when said elongated member is adjacent said longitudinally split distal end, said longitudinally split distal end expands, thereby affixing said hollow tube to said slide ring, and when said elongated member is removed from said longitudinally split distal end, said
longitudinally split distal end contracts, thereby allowing said hollow tube to be removed from said slide ring such that said device remains in said body lumen even after said hollow tube is removed.

24. (Withdrawn) The device of claim 2, wherein said reinforcement fibers are attached to said frame.

25. (Withdrawn) The device of claim 2, wherein said reinforcement fibers are attached to said frame by connections that are configured to form hinges in said frame.

26. (Withdrawn) The device of claim 2, wherein said frame is constructed to collapse and expand said composite structure.

27. (Withdrawn) The device of claim 1, wherein said membrane defines a plurality of holes therein to allow passage of a body fluid, while preventing passage of particles above a certain size.

28. (Withdrawn) The device of claim 27, wherein each of said plurality of holes is up to approximately 100 microns in diameter.

29. (Withdrawn) The device of claim 27, wherein said plurality of holes are arranged in a substantially repeating pattern in said membrane.

30. (Withdrawn) The device of claim 1, wherein the material making up said reinforcement fibers have a tensile stress and modulus of elasticity greater than the material making up said membrane.

31. (Withdrawn) The device of claim 1, wherein said reinforcement fibers comprise a plurality different fiber types, including fibers for shape control combined with fibers with high tensile strength.

32. (Withdrawn) The device of claim 1, wherein said reinforcement fibers are monofilament or multi-filament fibers.

33. (Withdrawn) The device of claim 1, wherein said reinforcement fibers are discontinuous and dispersed throughout said membrane.

34. (Withdrawn) The device of claim 1, wherein said reinforcement fibers are coated with a polymer to enhance adhesion between said reinforcement fibers and said membrane.

35. (Withdrawn) The device of claim 1, wherein said reinforcement fibers are glued to said membrane.

36. (Withdrawn) The device of claim 1, wherein the material making up said membrane comprises a polymer, an organic tissue, or a tissue of human or animal origin.

37. (Withdrawn) The device of claim 1, wherein the material making up said reinforcement fiber is selected from the group consisting of carbon, glass, ceramics, metals, metal alloys, polymers and combinations thereof.

38. (Withdrawn) The device of claim 1, further comprising a biocompatible material disposed on at least a portion of said device.

39. (Withdrawn) The device of claim 38, wherein said biocompatible material prevents the adherence of emboli or platelets to said device.

40. (Withdrawn) The device of claim 38, wherein said biocompatible material releases a drug into said body lumen.

41. (Original) The device of claim 1, wherein said composite structure is a filter that is expandable into an expanded state, said filter comprising a substantially closed distal end and an open proximal end such that said filter tapers from said proximal end to said distal end.

42. (Original) The device of claim 41, further comprising a reservoir in said filter that extends from said distal end, said reservoir defining a debris storage space.

43. (Withdrawn) The device of claim 2, wherein said frame allows said device to expand until a predetermined expanded size limit is reached.

44. (Withdrawn) The device of claim 43, wherein said reinforcement fibers are oriented in such a way as to give said composite structure a shape that depends, within predetermined limits, on the pressure difference across said composite structure.

45. (Withdrawn) The device of claim 1, wherein said device comprises a removable temporary stent, a dilator, a reamer, an arterial occlusion device, a graft housing, a valve, a surgical clip or a delivery platform for drugs, radiation or gene therapy.

46. (Withdrawn) The device of claim 1, wherein said membrane is substantially free of holes such that said membrane is substantially non-porous.

47. (Withdrawn) The device of claim 46, wherein said device comprises a skin for grafts, a stent, a catheter component, an inflatable member, a balloon pump, a retrieval bag or a body tissue replacement.

48. (Original) A medical device configured to be disposed within a body lumen, said device comprising:

a composite structure comprising:

a membrane; and

reinforcement fibers coupled to said membrane to form said composite structure;

a frame attached to said reinforcement fibers; and

an elongated member attached to at least one of said frame or said composite structure to facilitate movement of said composite structure into said body lumen.

49. (Withdrawn) The device of claim 48, wherein said frame is expandable such that in a first state, said frame and said composite structure define a first size profile that is configured to be transported by said elongated member to a desired location within said body lumen, while in a second state, said frame and said composite structure define a second size profile that is configured to engage said body lumen.

50. (Withdrawn) The device of claim 48, wherein said composite structure defines a plurality of holes in said membrane.

51. (Original) The device of claim 48, further comprising:

a first ring slidably disposed on said elongated member and coupled to a distal end of said composite structure;

a second ring slidably disposed on said elongated member and coupled to a proximal end of said frame; and

a plurality of stops affixed to said guide wire such that upon contact between one of said stops and one of said first or second rings due to movement of said elongated member, said device moves either into or out of said body lumen.

52. (Original) The device of claim 48, wherein said elongated member comprises a guide wire.

53. (Withdrawn) A vascular filter assembly comprising:

a filter comprising:

a membrane defining a plurality of holes therein; and

reinforcement fibers coupled to said membrane to form a composite structure;

an expandable frame attached to said reinforcement fibers; and

a guide wire attached to at least one of said frame or said filter to facilitate movement of said assembly into said body lumen.

54. (Withdrawn) The vascular filter of claim 53, wherein said guide wire is attached to each of said filter and frame.

55. (Original) A medical device configured to be disposed within a body lumen, said device comprising:

a composite structure comprising:

a membrane; and

first fibers coupled to said membrane to form said composite structure;

a frame attached to said composite structure;

second fibers coupled to said frame;

a guide wire coupled to said frame and said composite structure through said first and second fibers such that said first and second fibers and said guide wire are configured to move said composite structure and said frame.

56. (Original) The device of claim 55, wherein said first fibers comprise reinforcement fibers.

57. (Original) The device of claim 56, wherein said frame is attached to said composite structure through said reinforcement fibers.

58. (Original) The device of claim 55, wherein the material making up said first and second fibers is the same.

59. (Original) The device of claim 55, wherein said reinforcement fibers are discontinuous and dispersed throughout said membrane.

60. (Withdrawn) A medical device configured to be disposed within a body lumen, said device comprising:

a non-filter membrane; and

reinforcement fibers coupled to said membrane to form a composite structure therefrom.

61. (Withdrawn) A method of fabricating a medical device configured to be disposed within a body lumen, said method comprising:

providing a removable mold in substantially a shape of said device;

covering said mold with membrane material;

placing fibers in contact with said membrane material;

covering said fibers with additional membrane material to form a composite structure; and

removing said mold.

62. (Withdrawn) The method of claim 61, comprising the additional step of covering said mold with an intermediate material that is easily separated from said membrane material prior to said step of covering said mold with said membrane material.

63. (Withdrawn) The method of claim 62, comprising the additional step of removing said intermediate material from said membrane.

64. (Withdrawn) The method of claim 61, wherein said step of removing the mold is by melting,

dissolving, or deforming the mold.

65. (Withdrawn) The method of claim 64, wherein the mold is made of a material that dissolves in a liquid.

66. (Withdrawn) The method of claim 64, wherein the mold is made of a sheath filled with fine solid grains and then vacuum sealed.

67. (Withdrawn) The method of claim 61, wherein the mold is an expandable or inflatable structure.

68. (Withdrawn) The method of claim 61, further comprising coating said composite structure with an additional material having a property not possessed by the materials making up said composite structure.

69. (Withdrawn) The method of claim 61, comprising the additional step of connecting a frame to said composite structure.

70. (Withdrawn) The method of claim 69, wherein said step of connecting said frame to said composite structure comprises attaching said reinforcement fibers disposed in said composite structure to said frame.

71. (Withdrawn) The method of claim 69, wherein said frame is expandable.

72. (Withdrawn) The method of claim 70, comprising the additional step of connecting a guide wire to at least one of said frame or composite structure.

73. (Withdrawn) The method of claim 61, comprising the additional step of forming a plurality of

holes in said membrane.

74. (Withdrawn) The method of claim 73, wherein said step of forming holes is by laser drilling.

Evidence Appendix

None.

Related Proceedings Appendix

None.